SUMMARY OF FINDINGS

Inspection of this manufacturer of class 1 and 2 medical devices was conducted as a routine FY13 work plan assignment (FACTS #8690859). This was a level II QSIT inspection conducted per CP 7382.845 and FDA's *Guide to Inspection of Quality Systems*. The previous FDA inspection of this site conducted January 2011was classified NAI.

Upon arrival we presented credentials and a NOI to Mr. Michael J. Kochis, Site Manager and person identified as responsible for daily operations at the inspected site. The current inspection revealed that this Medrad, Inc. (dba Bayer R&I) site (known as the Heilman Center plant) continues to serve as Medrad's electro-mechanical assembly plant, producing injectors and pumps for the Radiology and Cardiovascular product lines. The plant also produces MR coils, repacks/re-labels MR physiological monitors, and provides depot level service of own and third party devices. Design cognizance for these products resides at Medrad's Indianola site. Some CAPA and complaint processing activities supporting these products also occurs at Medrad's corporate HQ in Warrendale, PA. Inspection of this site (electromechanical assembly) was the first of three sequential inspections of Medrad's Pittsburgh area producing facilities, the other two being Sterile Disposable production at the Saxonburg site, and the Indianola site (Friel Center – design and lower volume disposables). These three independently registered sites share a Quality Management System and Manufacturing Information system. Medrad, Inc. is operating as/ doing business as Bayer Radiology and Interventional (R&I) unit of Bayer HealthCare LLC (the parent organization). Current organizational structure is illustrated in the Exhibit 1 presentation materials. Mr. Sam Liang, CEO of Medrad, Inc., continues as the person ultimately responsible for operations of this facility.

This inspection covered Management Controls, CAPA and Production & Process Controls as applied to (b) (4) platforms. Medrad personnel participating substantially in the review activity included Tim Anderson, head of Quality Bayer R&I; Julia Mitchell, Director Commercial Quality; and Joe Kridgen, Deputy Director Operations Quality.

Firm History and Jurisdictional issues have been addressed and documented in previous EIRs, and are largely unchanged save some organizational and name changes relating to Bayer R&I superstructure. This site continues to engage in higher order electro-mechanical assembly, test, and depot level service.

Review of the Management Controls subsystem as applicable to E-M production revealed no significant departures from the requirements of the Quality System Regulation (QSR). Review of CAPA activities (complaint handling practices, processing and disposition of nonconforming material, and quality information analysis, trending and reporting) revealed no significant departures from the requirements of the QSR, or from MDR adverse event reporting requirements. Review of Production and Process control subsystem revealed no significant or systemic departures from the requirements of the QSR. Final functional test processes applied post-service was the particular process selected for scrutiny. This review included assessment of validation activities for ATE used in functional evaluation of systems post-service.

No FDA 483 was issued. Final discussions were brief given the absence of adverse findings. We advised the firm that inspection of sister facilities would continue the following week, and that

we intended to formally close-out each of the three inspections after inspecting the Friel Center (Indianola site) due to the inter-related nature of the three producing facilities.

ADMINISTRATIVE DATA

Inspected firm:	Medrad, Inc. dba Bayer R&I
Location:	625 Alpha Dr Pittsburgh, PA 15238-2819
Phone:	412-767-2400
FAX:	412-767-2818
Mailing address:	625 Alpha Dr Pittsburgh, PA 15238-2819
Dates of inspection:	7/30/2013, 7/31/2013, 8/1/2013,
Days in the facility:	3
Participants:	James M. O'Donnell, Investigator Dennis Hock, Investigator

This was a team inspection conducted by Investigators Jake O'Donnell and Dennis Hock. Mr. O'Donnell wrote this report. No samples were collected. A single Exhibit consisting of introductory presentation materials was collected and is attached as Exhibit 1 – to illustrate organizational structure.

Exhibits:

1) Copy of Introductory Presentation (includes organization charts)

Attachments:

1) FDA 482 Notice of Inspection

James M. O'Donnell, Investigator

Dennis Hock, Investigator